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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,083	03/12/2004	Charles S. Schasteen	048968-117958	8520

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,083	SCHASTEEN ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 19-102* is/are pending in the application.

4a) Of the above claim(s) *1,7,14-16,19-22 and 27-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8-13,23-26 and 102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is responsive to Applicant's amendment and response filed August 3, 2009. Claim 1, 7, 14-16, 19-22, and 27-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on January 16, 2007.

Claims 2-6, 8-13, 23-26 and 102 are under examination.

2. Applicant's declaration filed under 37 C.F.R. 1.132 filed August 3, 2009 is acknowledged.

Rejections Withdrawn

3. In view of Applicant's response, the following rejections have been withdrawn:

(a) rejection of claims 2-6, 8-10 and 23-26 under 35 U.S.C. 103(a), pages 2-10, paragraph 3.

(b) rejection of claims 11-13, pages 11-13, under 35 U.S.C. 103(a), pages 11-13, paragraph 4.

(c) rejection of claim 102, pages 13-16 under 35 U.S.C. 103(a), pages 13-16, paragraph 5.

Rejections Maintained

4. The rejection was on the grounds that claims 2-6, 8-10 and 23-26 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al *(WO 00/50072 published August 31, 2000)* in view of Alesina et al *(SU 1637882 A published March 30, 1991)*.

The rejection is reiterated below:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, 8-10 and 23-26 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al *(WO 00/50072 published August 31, 2000)* in view of Alesina et al *(SU 1637882 A published March 30, 1991, Abstract only)*.

Conkle et al teach methods of isolating and separating oocysts from *Eimeria* species (oocysts known to cause coccidiosis) (see the Abstract). Conkle et al teach that the methods of the invention are used to produce vaccines against avian coccidiosis (see the Abstract). Thus, Conkle et al teach the claim limitation that the host animals are from the class Aves. Conkle et al teach that encysted protozoa (oocysts) are obtained from feces, the suspensions or slurries can include significant amounts of undesirable suspended solids (pages 4-5). Conkle et al teach that the encysted protozoa require centrifugation and concentration of the protozoa (page 6). Conkle et al teach that the suspensions can include from about 1 up to about 20 weight percent solid or feces (page 5). Conkle et al teach that the separation methods of the invention include dense salt solutions including water and sodium chloride (page 5). Conkle et al teach that encysted protozoa need to be separated from suspension to achieved at least 70% encysted protozoa recovery (page 5). Conkle et al teach that encysted protozoa can be recovered or separated by salt flotation or gas flotation (page 5). Conkle et al teach that using salt flotation results in about 80 to 95 percent recovery (page 5). Conkle et al teach that the use of gas flotation results in about 20 to 90 percent recovery of encysted protozoa (page 7). However, Conkle et al teach that that gas flotation process rejects about 20 to 90 percent of encysted protozoa (page 7). Conkle et al teach that a need exists for a more efficient vaccination method (page 2). Conkle et al teach that this need would use other techniques to eliminate hazardous chemical such as potassium dichromate in processing the protozoa included in compositions used to vaccinate animals (page 2).

Conkle et al do not teach the use of hydrocyclones.

Alesina et al that hydrocyclones can be used for microorganism suspension separation (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use hydrocyclones because Alesina et al that hydrocyclones can be used for microorganism suspension separation, It would be expected, absent evidence to the contrary, that the used on hydrocyclones in a method of isolating and separating encysted protozoa (oocysts from *Eimeria*) would be effective at separating microorganism.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. Thus, the art recognizes that hazardous chemicals often are a problem in separation techniques known in the art. The prior art recognizes that the use of hydrocyclones is a method to separate materials. See Alesina et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

Applicant's Arguments

Applicant urges that the Office's obviousness rejection is not cured by resort to Alesina, either alone or in combination with the other cited references. Applicant urges that the declaration filed under 37 C.F.R. 1.132 has noted that the term microorganism is not an art-based equivalent for the term oocyst because Applicant asserts that there are a number of physical and structural differences. Applicant urges that Alesina et al do not discuss whether the microorganisms are live or dead before or after seperation. Applicant asserts that oocysts are more akin to fertilized eggs which are not yet

developed enough to be infective. Applicant urges that physically, oocysts are also much larger and are less dense than microorganisms such as bacteria, including structural differences in the outer membrane/cell wall that make oocyts substantially more fragile than bacteria.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed August 8, 2009 have been fully considered but they are not persuasive.

To address Applicant's comments regarding microorganisms and oocyt not being art equivalents, it should be noted that the question is not whether microorganisms and oocyts are art-recognized equivalents but whether or not oocyts can withstand the treatment of being separated by a hydrocyclone. Applicant has stated that oocysts are akin to fertilized eggs which are not yet developed enough to be effective. The Examiner disagrees with this assertion. Svensson et al *(Veterinary Parasitology, Volume 69, Issues 3-4, May 1997, pages 211-218)* teaches that oocysts from the *Eimeria* species (the same species used in the claimed invention) are considered to be very resistant to physical and chemical agents (page 212). Based on the teachings of the prior art, one of ordinary skilled in the art would reasonably conclude that oocysts are very resistant to chemical and physical agents.

To address Applicant's comment's regarding Alesina et al not teaching whether the microorganisms of the invention were dead or alive, the Examiner has provided the full translation of SU 1637882 (Alesina et al) and the document does not disclose that

the microorganisms have been killed or inactivated in any way. One of ordinary skill in the art would *not* reasonably conclude from the reading of Alesina et al that the microorganism used in their invention are dead.

To address Applicant declaration filed under 37 C.F.R. 1.1.32 submitted by Dr. Christopher D. Knight and Dr. Julia J. Dibner is insufficient to overcome the rejection of claims 2-6, 8-10 and 23-26 based upon as set forth in the last Office action. The declaration states that "Applicant's were skeptical about using hydrocyclones to separate oocysts because oocysts are fragile". As state above, as early as 1999, the art recognized that oocysts are very resistant to physical and chemical agents.

It should be remembered that Svensson et al is only used to establish the state of the art and what the art recognized about oocysts and chemical and physical agents.

In view of all of the above, this rejection is maintained.

5. The rejection was on the grounds that claims 11-13 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al and Alesina et al as applied to claims 2-6, 8-10 and 23-26 and further in view of Sjoerdsma et al *(U.S. Patent No. 4,399, 151 published August 16, 1983).*

Conkle et al and Alesina et al have been described previously.
Conkle et al and Singh et al et al do not teach the use of screens.
Sjoerdsma et al teach that mesh screens can be used to extract debris from biological material (Example 6, column 24).
It would have been *prima facie* obvious at the time the invention was made to include a mesh screen in the method of Conkle et al and Alesina et al as combined above because demonstrate that mesh screens are effective at separating debris or

contaminants from biological material. It would be expected, absent evidence to the contrary that using mesh screens would be an effective way to eliminate contamination from oocysts.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

Applicant's Arguments

Applicant urges that for the reasons set forth above, the case of prima facie obviousness has been rebutted.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed August 8, 2009 have been fully considered but they are not persuasive.

The Examiner's comments regarding Conkle et al in view of Alesina et al is set forth above.

Sjoerdema et al is used to address the claim limitation as set forth in claims 11-13.

It would have been *prima facie* obvious at the time the invention was made to include a mesh screen in the method of Conkle et al and Alesina et al as combined above because demonstrate that mesh screens are effective at separating debris or contaminants from biological material. It would be expected, absent evidence to the

contrary that using mesh screens would be an effective way to eliminate contamination from oocysts.

To address Applicant's comments regarding "viable oocysts", as stated above, the Examiner has provided the full translation of SU 1637882 (Alesina et al) and the document does not disclose that the microorganisms have been killed or inactivated in any way. One of ordinary skill in the art would *not* reasonably conclude from the reading of Alesina et al that the microorganisms used in their invention are dead.

This rejection is maintained for the reasons as set forth above.

6. The rejection was on the grounds that Claim 102 is rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al, Alesina et al and Sjoerdsma et al as applied to claims 2-6, 8-13 and 23-26 above and further in view of Kimura et al *(Journal of Protozoology Research, July 2000, Vol. 10, No.3, pp. 155-165) (Abstract only).*

Claim 102 is drawn to the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup.

The teachings of Conkle et al and Alesina et al have been described previously.

Conkle et al and Alesina et al do not teach the claim limitation "the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup".

Kimura et al teach a flotation technique using sucrose (see the Abstract). Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use the hydrocyclones as taught by Alesina et al and the sucrose flotation technique as taught by Kimura et al because Alesina et al teach using hydrocyclones are used to separate microorganisms and Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts. It would be expected, absent evidence to the contrary, that the use of hydrocyclones and

sucrose flotation in a method of separating and isolating oocysts would be a fast, effective way to isolate and separate encysted protozoa (oocysts from *Eimeria*) without the use of hazardous chemicals.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. The prior art recognizes that the use of hydrocyclones is a method to separate microorganisms. See Alesina et al. It is known in the art to use sucrose flotation to separate and isolate oocysts. See Kimura et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

Applicant's Arguments

Applicant urges that for the reasons set forth above, the case of prima facie obviousness has been rebutted.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed August 8, 2009 have been fully considered but they are not persuasive.

The Examiner's comments regarding Conkle et al, Alesina et al and Sjoerdsma et al is set forth above.

Kimura et al is used to address the claim limitation as set forth in claim 102.

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use the hydrocyclones as taught by Alesina et al and the sucrose flotation technique as taught by Kimura et al because Alesina et al teach using hydrocyclones are used to separate microorganisms and Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts. It would be expected, absent evidence to the contrary, that the use of hydrocyclones and sucrose flotation in a method of separating and isolating oocysts would be a fast, effective way to isolate and separate encysted protozoa (oocysts from *Eimeria*) without the use of hazardous chemicals.

To address Applicant's comments regarding "viable oocysts", as stated above, the Examiner has provided the full translation of SU 1637882 (Alesina et al) and the document does not disclose that the microorganisms have been killed or inactivated in any way. One of ordinary skill in the art would *not* reasonably conclude from the reading of Alesina et al that the microorganisms used in their invention are dead.

This rejection is maintained for the reasons as set forth above.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

8. No claims are allowed.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Primary Examiner, Art Unit 1645
October 25, 2009